VIEWPOINT

AI IN MEDICINE

The First AI Drug Prescriber

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In January 2026, Utah announced a first-of-its-kind partnership with an artificial intelligence (AI) company to prescribe medications without physician involvement. The system, sold by Doctronic, is designed to conduct a "comprehensive medical assessment" that "mirrors the clinical decision-making process a licensed physician would follow."[1] Initially focusing on prescription renewals, the software is slated to prescribe almost 200 drugs, including corticosteroids, statins, antidepressants, hormones, and anticlotting agents. This Viewpoint explores this pathbreaking entry of AI into clinical care, the role of the US Food and Drug Administration (FDA), and the associated legal, public health, and medical implications.

The Potential Benefits and Risks

There are potential benefits to AI prescribing in a world facing a long-term shortage of primary care physicians, as well as certain specialists. Medication nonadherence, thought to be complex and multifactorial,[2] significantly affects mortality and morbidity; for many chronic conditions, the public health goal is ensuring that patients access safe, effective drugs and continue receiving them as long as it is appropriate. A 2018 study found that nonoptimized medication regimens, including nonadherence, cost the US $528.4 billion annually.[3] Between 4% and 31% of patients fail to fill a first prescription,[4] and according to a 2009 study, of those who fill a first prescription, approximately 20% fail to obtain a refill.[5] Artificial intelligence could reduce pervasive medication errors, enhance process efficiency, and free physicians to focus on complex diagnostic tasks or human-to-human interactions.

However, technologic innovations can also cause harm, generate waste, and undermine the clinical relationship. They might also reduce the number of patient-clinician encounters and therefore opportunities for physicians to spot other problems and for patients to organically raise concerns and questions.

Although physicians must demonstrate competence through rigorous training and board certification, AI prescribers face no equivalent gatekeeper. Artificial intelligence companies generally do not publicly disclose their software's precise methodology for making or recommending medical decisions. In the Utah deal, generalizations were offered, including that the AI prescriber is "trained on established medical protocols," and that its algorithm continues to evolve through "[f]eedback loops."[1]

The company also claimed that across 500 urgent care telehealth cases (a different domain than what is planned for Utah), its AI prescriber matched board-certified clinicians' top primary diagnosis in 81% of instances and treatment decisions in 99.2%.[1] The study was not blinded because reviewing physicians were able to easily recognize AI-written notes. These results were produced by company-affiliated authors and have not appeared in a peer-reviewed publication.

Law on Prescribing Drugs

In the US system of governance, states have long maintained foundational laws for dispensing medicines, positioning licensed physicians and pharmacists as essential gatekeepers. Referencing these state laws, federal law requires that any drug that "is not safe for use except under the supervision of a practitioner licensed by law" must be dispensed only "upon a written prescription of a practitioner licensed by law" (21 USC §353).

Artificial intelligence prescribers are not licensed "practitioner[s]" of medicine; here, Utah has waived state requirements. Utah's regulatory sandbox waives state laws for businesses with novel ideas deemed potentially beneficial to consumers. Although Arizona, Kentucky, and Nevada have similar mechanisms—and Texas and Wyoming have industry-specific sandboxes—Utah's move is unique so far. Without the licensed practitioner's prescription, drugs become misbranded, making their sale a crime. It is unclear how the federal government will apply this law to entities unaffiliated with the drug manufacturer.

Federal Law on AI Medical Devices

Under the main FDA statute, an AI prescriber is an "instrument, apparatus, implement, [or] machine" clearly "intended for use in the cure, mitigation, treatment, or prevention of disease," which makes it an FDA-regulated medical device (21 USC §321). The 21st Century Cures Act of 2016 created exemptions for software involving administrative support, general wellness, or electronic record storage. For clinical software, the FDA has generally exercised enforcement discretion only for tools that aid physician decisions. By design, AI prescribers remove the physician, meaning that FDA oversight is required.

In the Utah deal, the company made no attempt to approach the FDA about the technology, instead invoking the idea that the FDA does not regulate the practice of medicine. Federal law and the FDA itself express that the FDA does not regulate the practice of medicine. But federal law also reinforces that medical devices and drugs must be legally marketed and used within a legitimate patient-clinician relationship (unless marketed over the counter). Federal law does not permit the replacement of physicians with unlicensed computers.

The current administration appears to be forgoing federal oversight. Since the 2025 inauguration, the executive branch has rescinded previous AI governance orders, encouraged the removal of policies that might impair innovation, and issued an executive order aimed at reducing federal funds for states that regulate AI.

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US Commissioner of Food and Drugs Marty Makary has emphasized the need for AI innovation. Given this antiregulatory environment for AI, the prospect of federal intervention against AI prescribers appears slim, absent significant public pressure.

Private Governance and Liability

As federal and state regulators retreat, private organizations have stepped in.[6] The Joint Commission recently released nonbinding guidance urging health care organizations to establish internal AI governance structures and rigorously measure outcomes.[7] The success of AI prescribers will ultimately depend on the acceptance of health systems, which should demand robust evidence of safety and effectiveness, optimally in the form of clinical trials.

Tort law remains a potential avenue for addressing patient harm because Utah's agreement leaves such remedies intact. However, injured patients face significant hurdles. Courts will have to determine whether AI is held to the same standard of care as a human physician.[8] A products liability lawsuit would typically require a plaintiff to show that there was a reasonable alternative design, a challenge for AI black-box technologies. Furthermore, companies might argue that patients "assumed the risk" of using the AI prescriber, but that is not a complete defense.[8]

The Collingridge Dilemma

Artificial intelligence prescribing would be safest under concurrent state and federal oversight. Yet Utah has granted a state waiver and FDA compliance has not been demonstrated. Other companies may take the lesson that they can bypass federal safety standards, and they may race into the market to ensure they are not left behind.

This dynamic illustrates the Collingridge dilemma in the social control of technology.[9] The dilemma has 2 horns. The first is the information problem: when a technology is early in its life cycle, it is easy to regulate, but its harmful social consequences are nearly impossible to predict. The second is the power problem: by the time harms become apparent, the technology is so entrenched in the economy and clinical workflow that control is prohibitively expensive or politically impossible.

We have seen this play out with tobacco. The FDA fell behind in regulating flavored e-cigarettes, which are now ubiquitous and have contributed to a youth e-cigarette epidemic. The sheer scale of the unauthorized market and the subsequent legal tactics used by tobacco companies turned premarket requirements into a mere technicality.[10] If AI prescribing becomes the industry standard before safety and liability frameworks are established, the power problem may render future regulation infeasible.

Conclusions

Although AI offers the promise of increased efficiency and expanded access, the evasion of legal obligations by early movers raises profound concerns. Incorporating AI into modern health care must be evidence based and responsible. Physicians and health systems should insist that AI technologies not be allowed to bypass longstanding legal guardrails governing medical products.

ARTICLE INFORMATION

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